

# Conducting Research in the Iraq Theater of Operation: Challenges and Possibilities

Presentation to the U.S. Army Session

Human Subjects Protection: DOD Unique Challenges

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# Overview

- Key Requirement for the conduct of DOD-supported research
- Regulatory challenge of conducting human subjects research in a COCOM
- Evolution of the Multi-National Corps-Iraq Assurance of Compliance
- Mission of the Deployed Combat Casualty Care Research Team (DC<sup>2</sup>RT)



# Key DOD Human Subjects Protection Requirements

- Institutions engaged in DOD-supported human subjects research must operate under an “Assurance of Compliance for Human Subjects Protection” – establishes a Human Research Protection Program (HRPP)
- All DOD-supported human subjects research must undergo a DOD-level human subjects protection review and approval



# Conducting Research in a COCOM: Many Challenges

- What constitutes the “Institution?”
- Who is the Institutional Signatory on the Assurance?
- What are the elements of the Human Research Protection Program (HRPP)?
  - Qualified PIs
  - HSP training
  - Review and approval processes
    - Scientific Review
    - Institutional Review Board
  - Monitoring
- Who is competent to consent in an acute trauma unit?
- How frequently do investigators rotate?



## Solution...

- Select a manageable size organization in CENTCOM
  - Multinational Corps Iraq (MNC-I) oversees the Army MTFs in Iraq
- Draft a MOA for CENTCOM Official and Army Surgeon General to allow limited healthcare research to be conducted in theatre
  - LTG Vines, 82<sup>nd</sup> Airborne (MNC- I CDR) entered into MOA with TSG to set up a HRPP process



# What is MNC-I?

- Multi-National Corps - Iraq, part of Multi-National Force - Iraq, is the tactical unit responsible for command and control of operations throughout Iraq.
- Iraq is divided into 6 major areas of responsibility maintained by forces from 26 countries.
- MNC-I is headquartered by the U.S. Army V Corps forward deployed to Camp Victory, Baghdad.



# MNC-I Commander's Intent

... clinical research conducted within MNC-I

- must be highly relevant to military medicine,
- must protect all human research subjects, and
- must not hinder ongoing combat operations or health service support to such operations.

Per draft 30<sup>th</sup> Medical Brigade Policy Memorandum #21, TF 30<sup>th</sup> Medical Brigade  
Commander's Policy regarding the Conduct of Human Subjects Research



# MNC-I Multiple Project Assurance

- Signatories
  - Institutional Official: MNC-I Surgeon
  - Chair, IRB: Brooke Army Medical Center
  - DoD Approving Official: COL DeKoning, ASG(FP) for OTSG



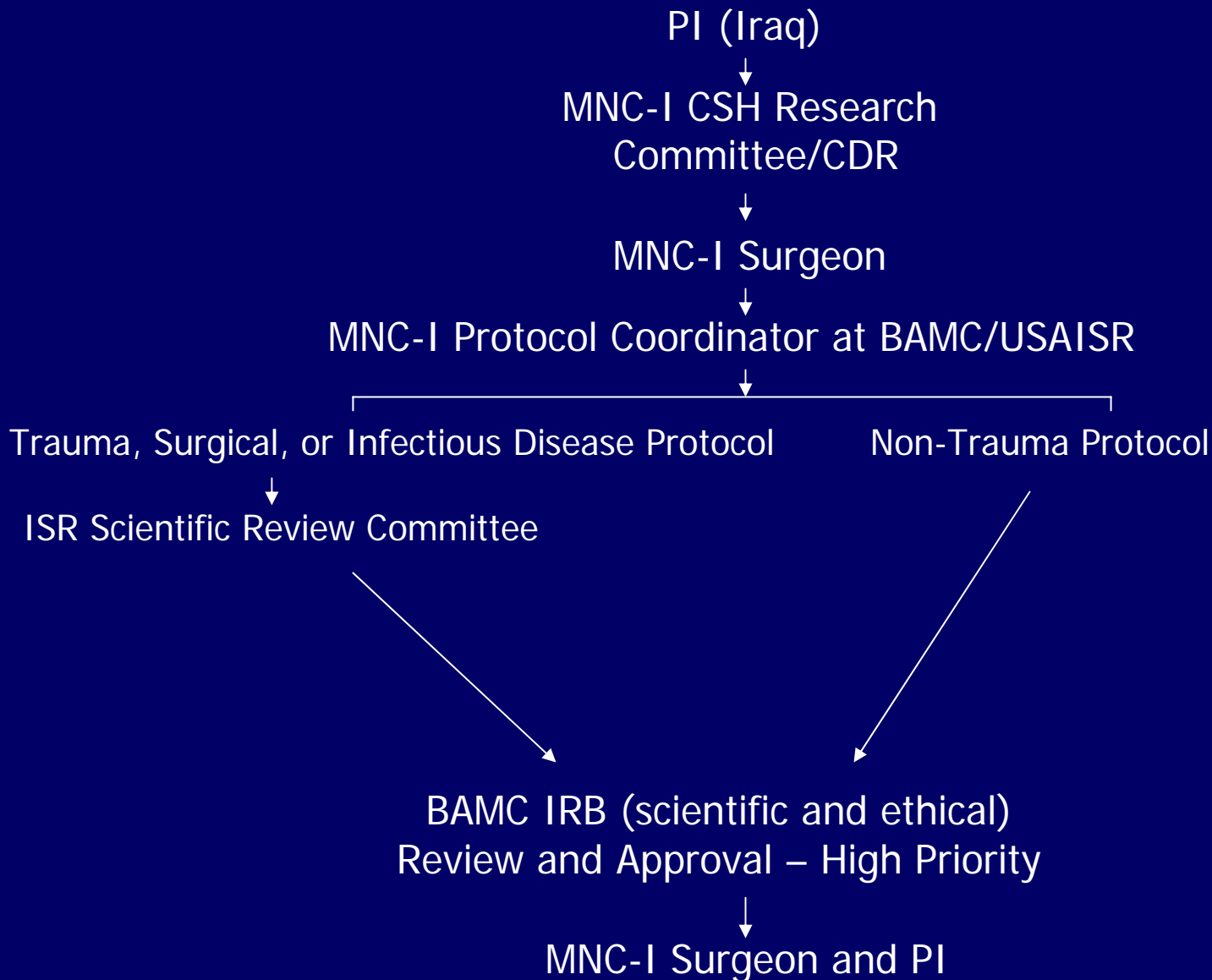


# MNC-I HRPP

- PIs must complete CITI Human Subjects Protection Training
- Protocols review by MTF Research Committee and GO from MTF Commander  
e.g., 28<sup>th</sup> CSH
- Review and “GO” from MNC-I Corps Surgeon
- ISR - scientific review
- Review and approval by the BAMC IRB
- HQ level review and approval by AMEDD C&S, CIRO



# Protocol Submission Pathway



# Types of Studies

- Retrospective Record Reviews
- Prospective studies with informed consent
- Prospective studies eligible for waivers of informed consent
- Utilization Reviews
- Retrospective Database Reviews (e.g. using Joint Theater Trauma Registry)



# Key Considerations...

- Why must the protocol be conducted in theatre? Is there an alternative research site that would provide more controlled conditions?
- Is the PI qualified to conduct the study? Is the study scientifically sound?
- Are the data available – e.g., will subjects be accessible for follow-up?
- Is the study feasible in the time allotted?
- Is the study acceptable to CENTCOM? – security, political sensitivity, etc.
- Does the study involve special categories of participants, e.g. local nationals?



# Timing

If research is anticipated prior to PI deployment:

- PI should perform literature review, decide upon methods & instruments
- Complete CITI training, [www.citiprogram.org](http://www.citiprogram.org)
- Contact [jeremy.perkins1@us.army.mil](mailto:jeremy.perkins1@us.army.mil) – on the ground with 28<sup>th</sup> CSH



# Important Considerations

- Note: Afghanistan is not part of MNC-I and there is not currently a Multiple Project Assurance for CFC-A
- Research involving POWs is prohibited
- Iraq Ministry of Health is in evolution – no mechanism identified to conduct research with host nationals at this point



# Future Directions

- Potential to include Air Force and Navy MTFs under the MNC-I Assurance
- Revise the MOA between MNC-I CDR to include Air Force and Navy if they wish to participate
- Develop Assurance for CENTCOM-Afghanistan that will provide support for medical research that theatre of operations



# Overview of the Deployed Combat Casualty Research Team (DC<sup>2</sup>RT)





# DC<sup>2</sup>RT MISSION

- First since Vietnam
- To conduct and facilitate timely and critical health care research within the Theater of Operation.
  - Support the MNC-I Surgeon, holder of the research assurance
- Mission accomplishment will include
  - increase IRB approved data collection and analyses
  - improve quality data acquisition
  - perform analyses that will positively impact healthcare delivery to the Warfighter



# Structure

- (1) Physician Researcher (O5-O6) - OIC, DC2RT, Principal Investigator (PI)
- (1) Nurse Researcher (PhD, O4-O5) - PI, Human Subjects Protection Coordinator, Educator
- (3) Professional Nurses (O2-O3) – Research coordinators, Data collection
- 
- (1) 91KP9 – (E-6) – NCOIC and lab liaison

Team Deployed o/a 8-10 Sep 06 embedded within the 28<sup>th</sup> CSH



# Deployed Combat Casualty Research Team (DC<sup>2</sup>RT)



- Mission: to conduct and facilitate timely and critical health care research within the Theater of Operation.



# Assignment and Deliverables

- Identify research priorities
- Develop protocols, capture and analyze data
- Inform, facilitate and coordinate research process in Theater
- Function as a research resource for the deployed medical force
- Augment real-time PI capabilities
- In concert with the JTTS implement data driven changes on near real-time basis
- Spread approved research activities to other MTF's in Iraq, Afghanistan and Kuwait



# Support in Theatre

- Direct support from the USAISR
  - Selection, training, supplies, equipment and scientific oversight (>\$55,000)
- Reach back to ISR and USAMRMC for research support
- Scientific Review and IRB support from ISR and BAMC as specified in the MNC-I Assurance



# Rotation

- 6 month cycle
- Volunteers recommended by Consultants
- By name tasking via MEDCOM Ops
- Team training at USAISR prior to deployment



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conclusions, and  
recommendations are those  
of the author and are not  
necessarily endorsed by the  
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